

the great heterogeneity caused by many treatment arms made it impossible to develop a feasible model to estimate incremental (cost-) effectiveness compared to other treatments. **CONCLUSIONS:** Outcomes research of bortezomib is complicated by extensive treatment variation and great patient heterogeneity in everyday practice. Although it is possible to generate evidence on appropriate drug use to facilitate informed decision making, much uncertainty remained regarding the incremental (cost-) effectiveness compared to other treatments. Policymakers should carefully consider if outcomes research could potentially lead to an acceptable reduction in decision-making uncertainty or that other options such as financial- or outcomes based risk sharing agreements might be more appropriate to obtain sufficient value for money.

PCN128

ESTIMATING THE VALUE OF COMPANION DIAGNOSTICS: ARE THE INCENTIVES RIGHT?

Nordyke RJ, Wang A, Zolfaghari S
PriceSpective LLC, El Segundo, CA, USA

OBJECTIVES: Targeted therapies are hoped to deliver high-quality, effective treatments that control cost growth. Companion diagnostics (CDs) – biomarker tests to identify patients likely to benefit – are key to this potential. However, as the US's IOM has noted, reimbursement for CDs may not provide optimal incentives to develop critical CDs. To illustrate, we examined the cost:benefit of CDs based on current reimbursement levels and the clinical and economic benefit allowed by biomarker targeting. **METHODS:** We identified 6 approved CD/therapeutic combinations, all in oncology. Several parameters were obtained: efficacy of therapeutic in indicated but otherwise un-targeted patients and in patients with the biomarker, therapeutic and diagnostic costs, and prevalence of the biomarker. CD clinical benefit was measured by the improvement in therapeutic efficacy in targeted versus untargeted patients. CD economic benefit was based on therapy cost avoided assuming that patients in a non-screened scenario undergo 1-month trial. To compare, we estimated a similar measure of the clinical cost:benefit for all oncology therapies approved since 2000. **RESULTS:** Estimated net economic benefit of CDs ranged from about \$250 to \$8,000. Estimated economic cost: benefit ranged from approximately \$0.05 to \$0.55 per USD saved. Estimates of the clinical cost:benefit of CDs ranged from approximately \$1.50 to over \$15 per one-percent improvement in clinical efficacy. Comparison oncology therapies are reimbursed at rates that imply an average clinical cost:benefit of about \$750 per one-percent improvement in efficacy for non-OS benefits to \$2400 per one-percent improvement in OS. **CONCLUSIONS:** Our calculations support the IOM statement that current reimbursement for CDs may not be optimal. Relative to the value placed on oncology therapeutics, the reimbursed value CDs is a small fraction of what would be expected under value-based pricing. This has implications for the structure of the CD industry as well as the potential for future innovations in diagnostics.

PCN129

EMERGING MARKET ACCESS TRENDS: PRICING AND COVERAGE OF TARGETED CANCER THERAPIES IN RUSSIA (2011-2012)

Aggarwal S
Novel Health Strategies, Bethesda, MD, USA

OBJECTIVES: In various emerging markets coverage of branded drugs is centralized using a national formulary list of covered products. Among new branded products pricing and coverage of expensive cancer drugs has been undergoing significant change in various emerging markets. The objective of this study was to understand new trends in pricing and coverage of targeted cancer therapies in Russia. **METHODS:** To understand the changes in coverage of targeted cancer therapies, the 2011 and 2012 essential drugs lists for Russia were analyzed for ATC codes L01XC, L01XE, L01XX, L04AA and L04AX. The newly covered and non-covered products were identified and analyzed for factors driving the change in coverage policy. For selected analogs price change during 2011 and 2012 was analyzed to understand trends in price set by the government. **RESULTS:** Analysis of 2011-2012 essential drug lists show significant change in coverage of targeted cancer therapies. In 2011, only 5 targeted cancer therapies were covered in the essential drug list (Bevacizumab, Rituximab, Trastuzumab, Imatinib and Bortezomib). In 2012, an additional 8 branded cancer drugs were added to the list, expanding the coverage of targeted cancer therapies to 13 products. The price change trend for selected analogs show some products covered at the same price while for others price was reduced by 5-10%. For example, for one of the covered monoclonal antibodies price did not change during 2011 and 2012, while prices for a proteasome inhibitor and a tyrosine kinase inhibitor were lowered by 6% and 10%, respectively. **CONCLUSIONS:** Analysis of pricing and coverage of targeted cancer therapies in Russia shows expansion of access of several products.

PCN130

ROLE OF THE HEALTH CARE PAYMENT SYSTEM ON THE PATIENT ACCESS TO ORAL ANTICANCER DRUGS: A COMPARISON OF FRENCH AND NORTH AMERICAN SITUATIONS

Benjamin L¹, Buthion V², Vidal-Trécan G³

¹University of Paris Descartes, School of Public Health (EHESP), GlaxoSmithKline, Marly le Roi, France, ²COACTIS EA 4161, University of Lyon, Lyon, France, ³Department of Public Health, Quality and Safety of care, Cochin Hospital, AP-HP, Paris, France

OBJECTIVES: Despite the convenience of oral anticancer drugs (OAD), several factors restrict the patient access to these treatments including the way the health care payment system (HPS) reimburses OAD or hospital services. From the French and American (U.S) experiences, we aimed at discussing how the HPS may create disincentives to the use of OAD. **METHODS:** A literature review was performed from Medline, Health Insurance reports, law articles, roundtable discussions to

analyze economic challenges of OAD in both systems. **RESULTS:** French hospitals are financed by the Health Insurance (HI) according to the nature and quantity of medical activities. Utilization of OAD shifts medical activities from hospital to community settings. 2 millions of intravenous (IV) chemotherapy sessions are performed yearly (i.e. 700 million Euros). A 10% decrease of IV chemotherapy sessions would induce an income loss of 70 million Euros for hospitals. The OAD also generates additional activities (therapeutic education, control of adherence/side effects ensuring a safe use) which are not considered in the payment of hospital activities. Although OAD are fully covered by the HI, physicians may be reluctant to prescribe OAD partly due to these economic constraints. In the U.S system, the reimbursement of OAD was limited to those with IV equivalence covered by the Medicare standard insurance. Since 2003, oral/IV chemotherapy parity legislation was adopted to provide beneficiaries with an extra-coverage (\$2850 covered with a 5% copay) but patients still have to support the cost of drugs before insurance claims, and may face with heterogeneous co-payments depending on private insurances, preventing those with low income to be treated with OAD. A 1% point reduction in cost-sharing would induce a 2.7% increase in OAD utilization. **CONCLUSIONS:** The adaptation of drug reimbursement systems and hospital financing are key issues to ensure equal and safe patient access to the most appropriate anticancer drugs.

PCN131

PRICING THEORY AND REALITY: THE LINK BETWEEN OUTCOMES AND PRICE

Wild L, Forster L
InterPhase P&MA, London, UK

OBJECTIVES: By utilizing health technology assessments to inform pricing and reimbursement decisions, payers hope to achieve prices that afford greater value to health care systems. To determine whether this theory holds true, we aimed to investigate the link between drug outcomes and pricing in EU5 markets both within and between therapy areas. **METHODS:** An initial screen of therapy areas was conducted to select relevant candidates for further analysis. A qualitative assessment was performed using criteria including: overall budget impact, number of high cost therapies available, number of new entrants and availability of objective measure of health outcomes. Based on this screen, oncology and diabetes were selected for further analysis and comparison. Ten of the most recent entrants were selected for further analysis in each therapy area. For each product, price premium relative to the most relevant comparator was calculated in EU5 markets, and compared to incremental change in outcome measures. In oncology, overall survival, progression free survival and time to progression were selected as outcome measures. In diabetes, HbA1c reduction, weight loss and proportion achieving HbA1c target were utilized. **RESULTS:** As expected, products displaying no or low incremental improvements received minimal price premiums relative to the comparator. However, although improved outcomes were associated with price premiums, the magnitude of this increase was not correlated to the degree of improvement. Furthermore, price premiums in oncology varied to a greater extent and reached higher levels relative to diabetes. **CONCLUSIONS:** This research indicates that in EU5 markets, drug pricing has not historically been pegged to health outcomes in a quantitative manner. With recent and forthcoming evolutions in pricing processes in Germany and the UK, future approvals in these and other therapy areas may display more “rational” pricing and deliver greater value to the health care systems.

PCN132

DURATION OF GEFITINIB TREATMENT IN EGFR MUTATION POSITIVE NSCLC PATIENTS IN A UK SINGLE PAYMENT ACCESS SCHEME (SPA)

Vioix H¹, Franzen S², Selby D¹, Hauch O³, Emmas CE¹

¹AstraZeneca UK Ltd., Luton, UK, ²AstraZeneca R&D, Mölndal, Sweden, ³AstraZeneca Pharmaceuticals LP, Wilmington, DE, USA

OBJECTIVES: The UK National Institute for Health and Clinical Excellence (NICE) recommended gefitinib for use first line in locally advanced or metastatic, EGFR mutation positive, NSCLC when supplied via the SPA scheme. This was based on the mean duration of treatment of 8.8 months observed in the IPASS study. The single fixed payment under the scheme is triggered at the order of the third pack and covers a patient for their total supply of gefitinib treatment. The objective of this study is to evaluate the length of gefitinib therapy and confirm the value accepted by NICE. **METHODS:** The SPA administrative database started in September 2009 to collect information on packs (30 days therapy/pack) dispensed to patients. This retrospective study includes patients fulfilling NICE eligibility criteria and with at least 12 months potential follow-up and for whom the NHS was invoiced. Median time to treatment cessation was estimated from a Kaplan-Meier curve of packs supplied to patients and mean number of packs dispensed from a parametric failure time model. **RESULTS:** 265 patients met the study eligibility criteria. These patients, for whom the NHS was invoiced the single fixed payment, received a median of 12 packs 95%CI[10,13] with a mean of 16.2 95%CI[14.1,18.6] packs per patient. **CONCLUSIONS:** The results of this observational study indicate that the average length of gefitinib therapy in UK clinical practice is at least as long as assumed under SPA which confirms the value accepted by NICE.

PCN133

UTILISATION OF ANTINEOPLASTIC AGENTS INVOLVED IN TREATMENT OF NSCLC IN SLOVAK REPUBLIC WITHIN 2008-2011

Bellova K¹, Gatialova K², Foltan V³, Majtás J⁴

¹Comenius University in Bratislava, Bratislava, Slovak Republic, ²Pharmaceutical Faculty at Comenius University, Bratislava, Slovak Republic, ³Faculty of Pharmacy, Comenius University, Bratislava, Slovak Republic, ⁴Comenius University, Bratislava, Slovak Republic